THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 35

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MILTON D. GOLDENBERG

Appeal No. 95-0206 Application 07/866,789¹

HEARD: August 5, 1997

Before MEISTER, JERRY SMITH and THIERSTEIN, <u>Administrative Patent</u> <u>Judges</u>.

JERRY SMITH, Administrative Patent Judge.

DECISION ON APPEAL

¹ Application for patent filed April 7, 1992, which is a continuation-in-part of Application 07/167,077, filed March 11, 1988, now U.S. Patent No. 5,101,827, issued April 7, 1992, which is a continuation of Application 06/751,877, filed July 5, 1985, now U.S. Patent No. 4,735,210 issued April 5, 1988.

Appeal No. 95-0206 Application 07/866,789

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's rejection of claims 1-7, which constitute all the claims remaining in the application.

The claimed invention pertains to a method of imaging hypoplastic, anatomically displaced or ectopic cells or tissues of a mammalian subject using scintigraphic or magnetic resonance imaging.

Representative claim 1 is reproduced as follows:

1. A method of imaging hypoplastic, anatomically displaced or ectopic cells or tissues in a mammalian subject by scintigraphic or magnetic resonance imaging, comprising the steps of: (a) parenterally injecting a mammalian subject, at a locus and by a route providing access to an organ of interest, with an antibody or antibody fragment which specifically binds a marker produced by or associated with said cell or tissue, said antibody or antibody fragment being labeled with a radioisotope or with a magnetic resonance image enhancing agent capable of external detection, the amount of the labeled antibody or antibody fragment being sufficient to permit a scintigraphic image or an enhanced magnetic resonance image of said organ to be obtained; and (b) obtaining a positive scintigraphic image or positive enhanced magnetic resonance image of said organ, at a time after injection of said agent sufficient for said agent to diffusely accrete in said organ and specifically bind to said marker.

The examiner relies on the following references:

Hansen et al. (Hansen)	3,927,193	Dec. 16, 1975
Goldenberg `647	4,331,647	May 25, 1982
Goldenberg `544	4,361,544	Nov. 30, 1982

Claims 1-7 stand rejected under 35 U.S.C. § 103. As evidence of obviousness the examiner offers Goldenberg '647 in view of Hansen and further in view of Goldenberg '544.

Rather than repeat the arguments of appellant or the examiner, we make reference to the briefs and the answer for the respective details thereof.

OPINION

We have carefully considered the subject matter on appeal, the rejection advanced by the examiner and the evidence of obviousness relied upon by the examiner as support for the rejection. We have, likewise, reviewed and taken into consideration, in reaching our decision, the appellant's arguments set forth in the briefs along with the examiner's rationale in support of the rejection and arguments in rebuttal set forth in the examiner's answer.

It is our view, after consideration of the record before us, that the collective evidence relied upon and the level of skill in the particular art would not have suggested to one of ordinary skill in the art the obviousness of the invention as set forth in claims 1-7. Accordingly, we reverse.

Appellant has indicated that for purposes of this appeal the claims will stand or fall together in the following two groups: Group I has claims 1, 3, 4, 6 and 7, and Group II has claims 2 and 5. Consistent with this indication appellant has

made no separate arguments with respect to any of the claims within each group. Accordingly, all the claims within each group will stand or fall together. Note In re King, 801 F.2d 1324, 1325, 231 USPQ 136, 137 (Fed. Cir. 1986); In re Sernaker, 702 F.2d 989, 991, 217 USPQ 1, 3 (Fed. Cir. 1983). Accordingly, we will only consider the rejection against claims 1 and 2 as representative of all the claims on appeal.

We consider first the rejection of claim 1 under 35 U.S.C. § 103. In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the examiner to establish a factual basis to support the legal conclusion of obviousness. See In re Fine, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In so doing, the examiner is expected to make the factual determinations set forth in Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), and to provide a reason why one having ordinary skill in the pertinent art would have been led to modify the prior art or to combine prior art references to arrive at the claimed invention. Such reason must stem from some teaching, suggestion or implication in the prior art as a whole or knowledge generally available to one having ordinary skill in the art. Uniroyal Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir.), cert. denied, 488 U.S. 825

(1988); Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.,
776 F.2d 281, 293, 227 USPQ 657, 664 (Fed. Cir. 1985), cert.
denied, 475 U.S. 1017 (1986); ACS Hospital Systems, Inc. v.
Montefiore Hospital, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). These showings by the examiner are an essential part of

complying with the burden of presenting a <u>prima facie</u> case of obviousness. <u>Note In re Oetiker</u>, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

In rejecting claim 1, the examiner noted that Goldenberg '647 taught a method for detecting and localizing tumors using radiolabeled antibodies specific to antigens which are produced or associated with the tumor. According to the examiner, the only features not taught by Goldenberg '647 were the emitting energy of the radioisotope [recited in claim 3] and the specific immunoreactivity of the antibody or fragment and the cross-reactivity to other antigens [recited in claim 7] [answer, page 3]. The examiner relied on Hansen for teaching the claimed emitting energy of the radioisotope and relied on Goldenberg '544 for teaching the claimed immunoreactivity and cross-reactivity to other antigens.

We note that neither of these latter features is specifically recited in claim 1. Even though the examiner applied the three references against all the claims on appeal, the examiner did not identify any specific recitation of claim 1 which was not disclosed by Goldenberg '647. The Hansen and Goldenberg '544 references appear to have been cited only to meet the limitations

of certain dependent claims as indicated above. Thus, the rejection of claim 1, as written, suggests that Goldenberg '647 fully meets the invention, which of course, would support a rejection on obviousness as well.

Appellant's main argument throughout has been that claim 1 is directed to the enhanced imaging of cells or tissues which may have no pathology associated therewith whereas the applied prior art is all directed to the enhanced imaging of tumorous cells and tissues. Appellant argues that the types of "healthy" tissues recited in claim 1 cannot be imaged by the methods described in the applied prior art. The examiner has taken the position that the imaging carried out by the applied prior art inherently involves observing normal as well as abnormal cells

and that such operation would meet the recitations of claim 1.

Appellant argues that inherency is not an appropriate ground for finding obviousness under 35 U.S.C. § 103.

Although appellant's argument on inherency is flawed, the examiner's finding of inherency is without factual support in the prior art of record. Claim 1 recites that a subject is injected with "an antibody or antibody fragment which specifically binds a marker produced by or associated with said cell or tissue." The antecedent basis for said cell or tissue is the recitation of "hypoplastic, anatomically displaced or ectopic cells or tissues" as recited in lines 1-2 of claim 1. Thus, the marker of the invention of claim 1 must be associated with a cell or tissue which is simply abnormally shaped, and not necessarily pathologically abnormal. On the contrary, each of the applied prior art references injects antibodies which bind to markers produced by

tumorous cells or tissues and would not bind to markers of cells which are simply abnormally shaped. Thus, not only is the method of claim 1 not inherently performed by the prior art references, but the prior art is specifically designed not to enhance the image of otherwise healthy tissues. In other words, the image of claim 1 enhances the appearance of healthy tissues while the

prior art references each enhances only the image of tumorous tissues. The examiner's finding that the method of claim 1 is inherently performed by the applied prior art is, therefore, clearly erroneous.

In summary, for the reasons just discussed there is clearly a difference between the invention of claim 1 and the methods taught by the applied prior art. The examiner's reliance on an inherency position fails to address why this difference would have been obvious to one having ordinary skill in the art. As noted above, an explanation of why differences between the claimed invention and the applied prior art would have been obvious is a necessary part of the examiner's burden of establishing a prima facie case of obviousness. Thus, the examiner's failure to properly address the noted difference between the prior art and the invention of claim 1 results in a failure to make a prima facie case of obviousness.

For all the above reasons, we do not sustain the examiner's rejection of claim 1 and of claims 3, 4, 6 and 7 which are grouped therewith. Since claims 2 and 5 include all the limitations of claim 1 based on their dependency therefrom, we also do not sustain the rejection of these claims. Accordingly, the decision of the examiner rejecting claims 1-7 under 35 U.S.C.

Appeal No. 95-0206 Application 07/866,789

§ 103 is reversed.

REVERSED

JAMES M. MEISTER Administrative Patent Judge)))
JERRY SMITH Administrative Patent Judge)) BOARD OF PATENT)) APPEALS AND
)) INTERFERENCES)
JOAN THIERSTEIN Administrative Patent Judge)

Bernhard D. Saxe Foley & Lardner 3000 K St., N.W., Suite 500 Washington, DC 20007-5109